IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF TEXAS
TYLER DIVISION

RETRACTABLE TECHNOLOGIES, INC.	§	
	§	
Plaintiff,	§	
	§	
vs.	§	**CASE NO. 6:08 CV 120**
	§	
OCCUPATIONAL & MEDICAL INNOVATIONS, LTD.	§	
	§	
	§	
Defendant.	§	

MEMORANDUM OPINION

This claim construction opinion interprets the disputed terms in U.S. Patent Nos. 6,572,584 ("the '584 patent") and 7,351,224 ("the '224 patent"). Appendix A contains the disputed terms, as they appear in the asserted claims of these patents. Appendix B contains a chart summarizing the Court's constructions.

BACKGROUND

Plaintiff Retractable Technologies, Inc. ("RTI") accuses Occupational & Medical Innovations, Ltd. ("OMI") of infringing claims of the '584 and '224 patents. Substantial portions of these patents' specifications are the same.[1] The '584 and '224 patents disclose a syringe that has a needle retraction mechanism that is triggered after an injection is complete. The retraction occurs through a spring-loaded needle holder within the syringe. A clamping or frictional force between the needle retraction mechanism and the inner wall of the syringe barrel holds the needle holder in

[1]For the purposes of the claim terms at issue, there is no consequence resulting from choices made to cite to the specification of the'584 or the '224 patent for material that is the same in both patents.

position during the administration of an injection. The frictional force opposes and exceeds the force of the spring. Upon completion of an administration, the plunger triggers the needle retraction by separation of the needle holder, which reduces the frictional force until the spring force is no longer opposed, whereupon the spring pushing on the needle holder causes the needle to retract into the barrel.

The '584 and '224 patents disclose two embodiments of a needle holder that separates upon contact by the plunger. In both embodiments, the needle holder has a retainer portion and a needle mounting portion, wherein the needle mounting portion separates from the retainer portion upon plunger contact. In the first embodiment, the retainer and needle mounting portion are held together by an interference fit. The plunger engages the retainer and causes it to slide off the needle mounting portion, which reduces the frictional force keeping the needle mounting portion in place. In the second embodiment, the retainer and needle mounting portion are coupled together by a bridge. The plunger engages the retainer and causes the bridge to fracture, which removes the frictional force keeping the needle mounting portion in place.

The '584 patent further discloses a technique to reduce the amount of plunger force needed to trigger the needle retraction mechanism. By tilting the retainer upon engagement with the plunger, the required plunger force is reduced because the plunger force is not applied uniformly across the retainer. The '584 patent discloses two embodiments for reducing required plunger force to trigger needle retraction. In the first embodiment, the plunger has a stepped face, and in the second embodiment, the plunger has an angled face. In both embodiments, a first portion of the plunger face moves the flat retainer surface before a second portion of the plunger face moves the remainder of the flat retainer surface.

This is not the first time terms in these patents have been construed. Judge David Folsom and this Court have both issued previous *Markman* opinions construing terms of the '584 and '224 patents. *See Retractable Techs. v. New Med. Techs.*, Nos. 4:02-CV-34, 4:03-CV-49, 2004 WL 435054 (E.D. Tex. March 3, 2004) (Davis, J.); *see Retractable Techs., Inc. v. Becton Dickinson & Co.*, No. 2:07-CV-250, slip op. (E.D. Tex. Jan. 20, 2009) (Folsom, J.).

APPLICABLE LAW

"It is a 'bedrock principle' of patent law that 'the claims of a patent define the invention to which the patentee is entitled the right to exclude.'" *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312 (Fed. Cir. 2005) (en banc) (quoting *Innova/Pure Water Inc. v. Safari Water Filtration Sys., Inc.*, 381 F.3d 1111, 1115 (Fed. Cir. 2004)). In claim construction, courts examine the patent's intrinsic evidence to define the patented invention's scope. *See id.*; *C.R. Bard, Inc. v. U.S. Surgical Corp.*, 388 F.3d 858, 861 (Fed. Cir. 2004); *Bell Atl. Network Servs., Inc. v. Covad Commc'ns Group, Inc.*, 262 F.3d 1258, 1267 (Fed. Cir. 2001). This intrinsic evidence includes the claims themselves, the specification, and the prosecution history. *See Phillips*, 415 F.3d at 1314; *C.R. Bard, Inc.*, 388 F.3d at 861. Courts give claim terms their ordinary and accustomed meaning as understood by one of ordinary skill in the art at the time of the invention in the context of the entire patent. *Phillips*, 415 F.3d at 1312–13; *Alloc, Inc. v. Int'l Trade Comm'n*, 342 F.3d 1361, 1368 (Fed. Cir. 2003).

The claims themselves provide substantial guidance in determining the meaning of particular claim terms. *Phillips*, 415 F.3d at 1314. First, a term's context in the asserted claim can be very instructive. *Id*. Other asserted or unasserted claims can also aid in determining the claim's meaning because claim terms are typically used consistently throughout the patent. *Id*. Differences among the claim terms can also assist in understanding a term's meaning. *Id*. For example, when a

dependent claim adds a limitation to an independent claim, it is presumed that the independent claim does not include the limitation. *Id*. at 1314–15.

"[C]laims 'must be read in view of the specification, of which they are a part.'" *Id*. (quoting *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 979 (Fed. Cir. 1995) (en banc)). "[T]he specification 'is always highly relevant to the claim construction analysis. Usually, it is dispositive; it is the single best guide to the meaning of a disputed term.'" *Id*. (quoting *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996)); *Teleflex, Inc. v. Ficosa N. Am. Corp.*, 299 F.3d 1313, 1325 (Fed. Cir. 2002). This is true because a patentee may define his own terms, give a claim term a different meaning than the term would otherwise possess, or disclaim or disavow the claim scope. *Phillips*, 415 F.3d at 1316. In these situations, the inventor's lexicography governs. *Id*. Also, the specification may resolve ambiguous claim terms "where the ordinary and accustomed meaning of the words used in the claims lack sufficient clarity to permit the scope of the claim to be ascertained from the words alone." *Teleflex, Inc.*, 299 F.3d at 1325. But, "'[a]lthough the specification may aid the court in interpreting the meaning of disputed claim language, particular embodiments and examples appearing in the specification will not generally be read into the claims.'" *Comark Commc'ns, Inc. v. Harris Corp.*, 156 F.3d 1182, 1187 (Fed. Cir. 1998) (quoting *Constant v. Advanced Micro-Devices, Inc.*, 848 F.2d 1560, 1571 (Fed. Cir. 1988)); *see also Phillips*, 415 F.3d at 1323. The prosecution history is another tool to supply the proper context for claim construction because a patent applicant may also define a term in prosecuting the patent. *Home Diagnostics, Inc., v. Lifescan, Inc.*, 381 F.3d 1352, 1356 (Fed. Cir. 2004) ("As in the case of the specification, a patent applicant may define a term in prosecuting a patent.").

Although extrinsic evidence can be useful, it is "'less significant than the intrinsic record in

determining the legally operative meaning of claim language.'" *Phillips*, 415 F.3d at 1317 (quoting *C.R. Bard, Inc.*, 388 F.3d at 862). Technical dictionaries and treatises may help a court understand the underlying technology and the manner in which one skilled in the art might use claim terms, but technical dictionaries and treatises may provide definitions that are too broad or may not be indicative of how the term is used in the patent. *Id*. at 1318. Similarly, expert testimony may aid a court in understanding the underlying technology and determining the particular meaning of a term in the pertinent field, but an expert's conclusory, unsupported assertions as to a term's definition is entirely unhelpful to a court. *Id*. Generally, extrinsic evidence is "less reliable than the patent and its prosecution history in determining how to read claim terms." *Id*.

CONSTRUCTION OF DISPUTED TERMS IN THE '584 AND '224 PATENTS[2]

Retainer and Needle Holder Relationship Terms

"retainer member" ('224 patent, claims 1, 20, 22)
"a continuous retainer member surrounding the inner head" ('224 patent, claim 43)
"the continuous retainer member" ('224 patent, claims 58, 60)
"transverse retainer" ('584 patent, claims 18-20, 24-25)

The claims of the '584 and '224 patents contain the terms "retainer member," "a continuous retainer member surrounding the inner head," "the continuous retainer member," and "transverse retainer" (collectively "retainer member terms"). The parties treat these terms as having the same meaning. Thus, the Court addresses these terms collectively. RTI contends that these terms mean "a non-retractable part of the retraction mechanism that uses some clamping or frictional force to keep the needle in the projecting position until released." OMI contends that the terms mean "a non-retractable part of the retraction mechanism, separate from the needle holder, that uses some

[2]The parties do not attempt to differentiate the meaning of the disputed claim terms between the '584 and '224 patents.

clamping or frictional force to keep the needle in the projecting position until released." The parties' only dispute is whether the non-retractable part of the retraction mechanism ("retainer") is "separate from the needle holder."

The retainer does not need to be separate from the needle holder. The claims do not contain this limitation, and the specification does not contain any language of disavowal limiting "retainer member" to being separate from the needle holder. *See Becton Dickinson*, at 14-15 (holding that there is nothing in the specification that requires the needle holder and retainer member be two separate parts and that the specification only shows possible embodiments of a separable retainer). OMI argues that the Summary of the Invention shows that the retainer must be separate from the needle holder. OMI asserts that every time that the Summary of the Invention discusses the invention with a retainer, the retainer is separate from the needle holder. However, "[a]bsent a clear disavowal or contrary definition in the specification or the prosecution history, the patentee is entitled to the full scope of its claim language." *See Linear Tech. Corp. v. Int'l Trade Comm'n*, 566 F.3d 1049, 1055 (Fed. Cir. 2009) (citing *Home Diagnostics, Inc. v. LifeScan, Inc.*, 381 F.3d 1352, 1358 (Fed. Cir. 2004)). OMI's asserted excerpts only refer to "one embodiment," "an alternate construction," and "an alternate embodiment" of the invention. *See* '584 patent, 3:50-58; 3:64-4:4; 5:5-12. This is language of possibility rather than enforceable language of disavowal. Thus, the Summary of the Invention does not create a limitation that the retainer member must be separate from the needle holder.

OMI also argues that the prosecution history shows that the retainer must be separate from the needle holder. OMI asserts that the applicant stated in a response to an office action that "[t]he retainer member (66) is not the same as the needle holder (22)." Def.'s Br. (Docket No. 89) Ex. 8,

Amendment and Reps. to Office Action, 9. However, this statement does not demonstrate clear disclaimer in the context of the office action. Stating that the retainer is not the same as the needle holder does not necessarily mean that the retainer is separate from the needle holder. Rather, it simply means that the retainer is considered to be a part that is *distinct* from the needle holder. This meaning does not mandate *separation* from the needle holder. Thus, the applicant's statement left open the possibility that the retainer is not separate from the needle holder. As a result, the prosecution history does not show that the retainer must be separate from the needle holder. Accordingly, the Court rejects OMI's proposed limitation that the retainer must be separate from the needle holder. The parties otherwise agree on the construction of "retainer member," and the Court construes the "retainer member terms" as "a non-retractable part of the retraction mechanism that uses some clamping or frictional force to keep the needle in the projecting position until released."

Plunger Configuration

"first forwardly extending side configured to contact and move the first side of the retainer member relative to the needle holder and barrel"[3] **('584 patent, claim 1)**

"second forwardly extending side [of the front tip of the plunger] configured to thereafter contact and move the second side of the retainer member relative to the needle holder and barrel"[4] **('584 patent, claim 1)**

"providing a plunger having a front edge on the front tip portion configured to push on one

[3]RTI contends "first forwardly extending side configured to contact and move the first side of the retainer member relative to the needle holder and barrel" means "the first forwardly extending side is shaped or designed to contact and move the first side of the retainer member." OMI proposes the term means "the modified front tip of the plunger is an irregular shape designed such that one portion of the tip is advanced beyond the remainder of the tip to contact and move the first side of the retainer member."

[4]RTI contends "second forwardly extending side [of the front tip of the plunger] configured to thereafter contact and move the second side of the retainer member relative to the needle holder and barrel" means "the second forwardly extending side is shaped or designed to thereafter contact and move the second side of the retainer member." OMI contends the term means "the modified front tip of the plunger is an irregular shape designed such that one portion of the tip is advanced beyond the remainder of the tip to thereafter contact and move the second side of the retainer member."

portion of the retainer before pushing on the rest"[5] ('584 patent, claim 18)

"the plunger is configured with a front edge"[6] ('584 patent, claims 20, 27)

"providing a plunger having a front edge on the front tip portion configured to slide one portion of the outer edge of the transverse retainer with respect to the front of the barrel before beginning to move the rest"[7] ('584 patent, claim 24)

The claims of the '584 patent contain the above "plunger configuration" terms. RTI proposes using substantially the same language as the claim terms themselves, only changing "configured" to "is shaped or designed." OMI proposes substantially the same language as RTI but adds that the plunger tip has "an irregular shape designed such that one portion of the tip is advanced beyond the remainder of the tip." RTI opposes using OMI's added language as improperly limiting the plunger tip. Thus, the parties dispute whether the plunger tip has "an irregular shape designed such that one portion of the tip is advanced beyond the remainder of the tip."

No construction is necessary for the "plunger configuration" terms. The claim terms themselves state the limitations of the plunger. Claim 1 states

> the front tip of the plunger having a longitudinally varying front surface comprising a first forwardly extending side configured to contact and move the first side of the

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[5]RTI contends "providing a plunger having a front edge on the front tip portion configured to push on one portion of the retainer before pushing on the rest" means "the front edge of the plunger is shaped or designed to push on one portion of the retainer before pushing on the rest." OMI contends the term means "the modified front tip of the plunger is an irregular shape designed such that one portion of the tip is advanced beyond the remainder of the tip to push on one portion of the retainer before pushing on the rest."

[6]RTI contends "the plunger is configured with a front edge" means "the plunger is shaped or designed with a front edge." OMI contends the term means "the modified front tip of the plunger is an irregular shape designed such that one portion of the tip is advanced beyond the remainder of the tip."

[7]RTI contends "providing a plunger having a front edge on the front tip portion configured to slide one portion of the outer edge of the transverse retainer with respect to the front of the barrel before beginning to move the rest" means "the front edge of the plunger is shaped or designed to slide one portion of the outer edge of the transverse retainer with respect to the front of the barrel before beginning to move the rest." OMI contends the term means "the modified front tip of the plunger is an irregular shape designed such that one portion of the tip is advanced beyond the remainder of the tip to slide one portion of the outer edge of the transverse retainer with respect to the front of the barrel before beginning to move the rest."

> retainer member relative to the needle holder and the barrel, and a second forwardly extending side disposed rearwardly of the first forwardly extending side, the second forwardly extending side configured to thereafter contact and move the second side of the retainer member relative to the needle holder and the barrel when the plunger is moved forwardly relative to the barrel.

'584 patent, Col. 25:38-48. Claim 18, dependent on claim 1, states

> providing a plunger having a front edge on the front tip portion configured to push on one portion of the retainer before pushing on the rest of the retainer when the plunger is pushed forward at the end of an injection.

'584 patent, Col. 27:23-26. Claim 20 states

> The method of claim 18 wherein the plunger is configured with a front edge comprising an opening and a stepped rim around said opening having a high step and a lower step wherein the step of pushing the plunger forward comprising the step of bringing the high step into first contact with the transverse retainer before the lower step contacts the transverse retainer.

'584 patent, Col. 27:40-46. Claim 24 states

> providing a plunger having a front edge on the front tip portion configured to slide one portion of the outer edge of the transverse retainer with respect to the front of the barrel before beginning to move the rest of the retainer with respect to the front of the barrel when the plunger is pushed forward at the end of an injection.

'584 patent, Col. 28:14-19. On their face, these claims expressly and clearly state the limitations of the plunger, including the plunger tip. Thus, no construction is necessary.[8]

OMI contends that the claims themselves show that the plunger tip has an "irregular" shape such that one portion of the tip is advanced beyond the remainder of the tip. OMI asserts that the claims recite a plunger tip that is configured so that a portion of the tip contacts one portion of the retainer prior to contacting the rest of the retainer. OMI concludes from the claims language that one

[8]This conclusion essentially adopts RTI's position. RTI used the claim language in its constructions except for changing "configured" to "is shaped or designed." This is not a substantive change. Furthermore, no construction is necessary to construe "configured" because "configured" has a plain and ordinary meaning that the jury would understand without explanation.

portion of the tip must be advanced beyond the remainder of the tip. OMI misconstrues the claim language. As cited above, claim 1 states the plunger tip contacts and moves one side of the retainer member and then contacts and moves the second side of the retainer member. Claim 18 states that the plunger tip pushes on one portion of the retainer before pushing on the rest of the retainer. Claim 20 states the step of bringing the high step of the plunger tip into first contact with the transverse retainer before the lower step contacts the transverse retainer. Claim 24 states the plunger tip sliding one portion of the outer edge of the transverse retainer before beginning to move the rest of the retainer. These excerpts do not reflect structural limitations on the plunger tip. Instead, they state action limitations that require the plunger tip to move one portion of the retainer member before moving the rest of the retainer member. In the context of these claims, these action limitations do not necessitate a structural limitation where the plunger tip must have an "irregular" shape. Accordingly, the plunger tip is not limited to having an "irregular" shape such that one portion of the tip is advanced beyond the remainder of the tip.

OMI also contends that the specification limits the plunger tip to having an "irregular" shape. OMI asserts that the Summary of the Invention states "The modified front tip of the plunger is an irregular shape configured such that one portion of the tip is advanced beyond the remainder of the tip." '584 patent, Col. 5:22-28. OMI also points to preferred embodiments including figures 17 and 19 that show two embodiments, one "having a high step [206] and a lower step [208] with the high step being a forwardly extended portion of the tip [202]" (figure 17) and the other where "the longitudinally varying front surface [220] is generally angled with respect to the longitudinal axis of the syringe such that one part of the front surface of the tip first presses against part of the retainer member when the plunger moves forward at the end of an injection." '584 patent, Col. 5:38-48.

OMI also asserts that the Summary of the Invention states "The beauty of the present invention is that a way has been found to reduce the force on the plunger required to retract the syringe without making any changes whatsoever to the retraction mechanism itself." '584 patent, Col. 23:31-34. OMI argues that this excerpt indicates that the "irregular" plunger tip is a key aspect of the '584 patented invention and should be limited accordingly.

OMI fails to demonstrate clear disavowal in the specification. First, the Summary of the Invention only describes the plunger tip as having an "irregular" shape without any suggestion that the patentee intended the claims to be limited by this description. Second, the preferred embodiments do not limit the claims because the patentee did not use any language of disavowal that would render the figures or the preferred embodiments limiting. Third, OMI's citation regarding the "beauty of the invention" does not necessitate that the plunger tip has an "irregular" shape such that one portion of the tip is advanced beyond the remainder of the tip. The "beauty of the invention" excerpt only states that "*a way* has been found to reduce the force on the plunger required to retract the syringe without making any changes whatsoever to the retraction mechanism itself." Meanwhile, this excerpt does not specify that the "way" to reduce the force required to retract the syringe requires an "irregular" shaped plunger tip. Accordingly, OMI has not demonstrated that the specification limits the plunger tip to having an "irregular" shape.

Finally, OMI contends that the prosecution history shows that the plunger tip has an "irregular" shape. OMI asserts that the applicant distinguished the claimed invention as having a front surface on the plunger that "whether stepped or substantially angled, longitudinally varies relative to the longitudinal axis of the barrel." Def.'s Br. (Docket No. 89) Ex. 10, Resp. to Office Action, 10. OMI also asserts that in the applicant's response to overcome an obviousness rejection

of claims 18 and 24, the applicant argued that the modified plunger rendered the claimed invention nonobvious. The applicant stated that testing syringes with modified plungers "yields unexpected results to those skilled in the art," specifically, "a very substantial reduction in the average plunger retraction force." The applicant also stated that these results were "momentous." Def.'s Br. (Docket No. 89) Ex. 10, Resp. to Office Action, 14. OMI concludes that the applicant's statements in the prosecution history limited the plunger tip to having a modified "irregular" shape. However, the language that OMI cites in the specification does not distinguish the prior art based on the plunger tip having an "irregular" shape. Instead, the applicant stated that the invention longitudinally varies relative to the longitudinal axis of the barrel. Longitudinally varying does not necessitate one portion being advanced beyond the remainder of the tip. In fact, OMI's citation matches the claim language in claim 1 that states "the front tip of the plunger having a longitudinally varying front surface." '584 patent, Col. 25:38-39. Thus, OMI's argument supports that no construction is necessary. Also, stressing the importance of the modified plunger does not insinuate anything about the actual shape of the plunger tip. Accordingly, OMI has not demonstrated that the prosecution history limits the plunger tip to having an "irregular" shape.

Given that the limitations on the plunger, including the plunger tip, are clear in the claims and that the specification and the prosecution history do not demonstrate a clear intention of the applicant/patentee to limit the plunger tip to an "irregular" shape, no construction is necessary.

Front Tip

"the plunger head further comprises a tip" ('224 patent, claim 4)
"front tip" ('584 patent, claims 1, 5, 6, 18, 21-24)

The claims of the '584 and '224 patents contain the terms "the plunger head further

comprises a tip" and "front tip" (collectively "front tip"). The parties treat these terms as having the same meaning. Thus, the Court addresses these terms collectively. RTI contends that "front tip" means "portion of the plunger closest to the needle." OMI contends that "front tip" means "the smaller diameter portion of the plunger that is forward of the plunger seal." The parties dispute whether "front tip" must be the "smaller diameter portion" of the plunger and whether the "front tip" must be "forward of the plunger seal."

The specification shows that "front tip" is the "portion of the plunger closest to the needle." The specification consistently refers to the tip of the plunger as the part of the plunger that is closest to the needle. The specification states "Head 34 [of the plunger] has a tip portion 40 forming an opening 41 into retraction cavity 38." '224 patent, Col. 7:28-29; *see also* '224 patent, Col. 11:55-56 (making the same statement); *see also* '584 patent, Col.8:36-37 (making the same statement); *see also* '584 patent, Col. 12:62-63 (making the same statement). Also, OMI does not contest that the tip is the portion of the plunger closest to the needle.[9] Accordingly, the Court construes "front tip" as "portion of the plunger closest to the needle."

OMI contends that the "front tip" must be smaller in diameter than the rest of the plunger and be located forward of the plunger seal. OMI argues that various embodiments described in the specification show a tip smaller in diameter than the rest of the plunger and positioned forward of the plunger seal. *See* '584 patent, figures 1-3, 8, 17-24. OMI also points to the Background of the Art that states "A head end which acts like a piston when installed in a syringe barrel has a reduced

[9]OMI argues that construing "front tip" as "the portion of the plunger closest to the needle" would render the claims meaningless because the claims already recite that the head of the plunger is closest to the needle. OMI also argues that the "tip" is a different portion from the "head" of the plunger. These arguments do not attempt to contradict that the "front tip" is the "portion of the plunger closest to the needle."

diameter front end having an opening and a dislodgeable stopper slidingly mounted in the opening projecting forwardly from the tip" and the Summary of the Invention that states "The nose has a reduced diameter relative to the barrel." '584 patent, Col. 2:32-37; Col. 3:6-7. Finally, OMI argues that because the plunger tip comes in contact with the retainer and the retainer is mounted in the most constricted portion of the barrel where the nose begins to provide high blowout pressure resistance, the tip of the plunger must necessarily have a smaller diameter than the rest of the plunger.

However, none of OMI's references to the patent warrant limiting the "front tip" to being smaller in diameter than the rest of the plunger and positioned forward of the plunger seal. Figures 1-3, 8, and 17-24 of the '584 patent only show possible embodiments of the "front tip," and the specification does not otherwise state that the figures show limiting features of the "front tip." Also, OMI's citations to the Background of the Art and the Summary of the Invention are not persuasive. These excerpts only refer to the barrel having "a reduced diameter" and do not refer to the front tip. Finally, OMI's argument regarding contact with the retainer and high blowout resistance does not mandate that the front tip be smaller in diameter than the rest of the plunger. The tip can be in the narrowed section of the barrel for blowout protection, and at the same time, not be smaller in diameter than the rest of the plunger. Given that OMI is unable to point to any language clearly limiting that the "front tip" must be smaller in diameter than the rest of the plunger and positioned forward of the plunger seal, the Court does not import these limitations into the claims and omits them from the Court's construction.

Forward Movement of the Needle

"needle holding portion is grounded inside the nose adjacent to the first open end by a barrier limiting forward motion of the elongated needle holder inside a front portion of the nose prior to or during retraction"[10] ('224 patent, claim 1)

"a barrier disposed in the front end portion of the body that limits forward motion of the needle holding portion and the retractable needle relative to the body as the plunger is depressed inside the barrel during injection and retraction"[11] ('224 patent, claim 43)

"the needle holding portion is grounded on the annular shoulder"[12] ('224 patent, claim 52)

The claims of the '224 patent contain the above "forward movement of the needle" terms. The parties dispute whether "limiting," "limits," and "grounded" mean the needle holder's forward movement is merely limited or if the needle holder is entirely prevented by an obstruction.

The prosecution history shows that the needle holder does not move forward once grounded. "'[A] clear and unmistakable disavowal of scope during prosecution' may affect the construction of a claim term." *Lucent Techs., Inc. v. Gateway, Inc.*, 525 F.3d 1200, 1211 (Fed. Cir. 2008) (citations omitted). The applicant stated "If needle (3) can still move forwardly during retraction, it does not appear to be 'grounded inside the nose' and a patient could be expected to experience pain as the

[10]RTI contends "needle holding portion is grounded inside the nose adjacent to the first open end by a barrier limiting forward motion of the elongated needle holder inside a front portion of the nose prior to or during retraction" means "the needle holder abuts an obstruction in the nose of the syringe which limits forward movement by the needle holder prior to or during retraction." OMI contends the term means "the needle holder abuts an obstruction in the nose of the syringe which prevents any forward movement by the needle holder prior to or during retraction."

[11]RTI contends "a barrier disposed in the front end portion of the body that limits forward motion of the needle holding portion and the retractable needle relative to the body as the plunger is depressed inside the barrel during injection and retraction" means "a structure located near the front end of the body that serves to limit forward movement of the needle holder prior to or during retraction." OMI contends the term means "a structure located near the front end of the body that serves to prevent any forward movement of the needle holder prior to or during retraction."

[12]RTI contends "the needle holding portion is grounded on the annular shoulder" means "the needle holder abuts a structure of reduced diameter within the syringe body." OMI contends the term means "the needle holder is prevented from moving forward by a structure of reduced diameter within the syringe body prior to or during retraction."

needle moves forward in relation to the needle assembly (9) as the plunger is fully depressed during retraction." Def.'s Br. (Docket No. 89) Ex. 11, Amendment and Resp., 36. The applicant later stated "Pressly et al. '629 does not disclose a syringe having a needle retraction mechanism grounded inside the nose adjacent to the first open end as recited in claim 58." Def.'s Br. (Docket No. 89) Ex. 11, Amendment and Resp., 38. Thus, the applicant established that when the needle is grounded, it cannot move forward, and the applicant expressed clear disavowal when he distinguishing from the prior art that the needle assembly, which includes the needle holder, cannot move forward during retraction if it is grounded inside the nose.

The specification supports construing "limit" and "grounded" as "prevent any forward movement." The Summary of the Invention states "The front of the needle holder is grounded in the nose portion *against forward movement*." '224 patent, Col. 4:6-7 (emphasis added). The Detailed Description of the Preferred Embodiment is consistent with the Summary of the Invention. The Detailed Description of the Preferred Embodiment states "Since the front portion 26 of the needle holder is grounded or bottomed inside front 76 of nose 16 at annular shoulder 77, *no amount of pressure will allow needle holder 22 or needle 28 to move forward*." '224 patent, Col. 8:27-30. Thus, the specification supports that the needle holder does not advance forward at all when grounded.

RTI contends that because dependent claim 52 (dependent on claim 50, which depends on claim 43) already contains the limitation "grounded on the annular shoulder," OMI's construction, which equates "limiting" (found in claim 43) with "grounded" would render claim 52 meaningless. '224 patent, Col. 24:9-10. However, OMI's construction is consistent with claim 52. The presumption created by claim differentiation requires "only that at least one limitation must differ."

Kraft Foods, Inc. v. Int'l Trading Co., 203 F.3d 1362, 1368 (Fed. Cir. 2000) (citation omitted). Claim 52 specifies that *contact between the needle holder and the annular ring* prevents forward movement of the needle holder. Contact between the needle holder and the annular ring is the required difference between claim 43 and claim 52 under the doctrine of claim differentiation. Thus, claim 43 and claim 52 may both prevent forward movement of the needle holder. Furthermore, any presumption created by claim differentiation is rebutted by the specification and prosecution history discussed *supra*. Thus, OMI's construction properly equates "limit" to "grounded."

RTI also contends that the original claim 30, which was cancelled prior to issuance, used the language "prevents forward motion of the retractable needle during retraction." Pl.'s Br. (Docket No. 79) Ex. 6, Amendment in Resp. to Non-Final Office Action, 38. RTI concludes from this that the applicant actually used the word "prevent" when he wanted to convey the meaning of "prevent"; thus, the applicant did not intend for other words, like "limit" and "grounded," to carry the meaning of "prevent." However, original claim 30 was cancelled, and RTI does not present evidence on the reason for cancellation. Thus, the intentions of the applicant and the examiner regarding the cancellation are unknown. This drastically reduces the persuasive value of original claim 30 because RTI only hypothesizes why the applicant used "prevent" in claim 30 and such a hypothesis alone does not establish clear disavowal. Accordingly, the "prevent" language in original claim 30 does not contradict RTI's proposed language "prevent any forward movement of the needle holder."

Accordingly, the Court construes "needle holding portion is grounded inside the nose adjacent to the first open end by a barrier limiting forward motion of the elongated needle holder inside a front portion of the nose prior to or during retraction" as "the needle holder abuts an obstruction in the nose of the syringe which prevents any forward movement by the needle holder

prior to or during retraction," "a barrier disposed in the front end portion of the body that limits forward motion of the needle holding portion and the retractable needle relative to the body as the plunger is depressed inside the barrel during injection and retraction" as "a structure located near the front end of the body that serves to prevent any forward movement of the needle holder prior to or during retraction," and "the needle holding portion is grounded on the annular shoulder" as "the needle holder is prevented from moving forward by a structure of reduced diameter within the syringe body prior to or during retraction."[13]

Location of the Spring

"compressed retraction spring is positioned prior to retraction in an annulus disposed between the needle holding portion and the inside wall of the hollow body" ('224 patent, claim 1)

"a compressed retraction spring surrounding at least part of the elongated needle holding portion" ('224 patent, claim 43)

Claim 1 of the '224 patent contains the term "compressed retraction spring is positioned prior to retraction in an annulus disposed between the needle holding portion and the inside wall of the hollow body." Claim 43 of the '224 patent contains the term "a compressed retraction spring surrounding at least part of the elongated needle holding portion." The parties dispute whether the "hollow body" is the "syringe body," (RTI's position) or the "nose" (OMI's position).

The claim language only requires the "compressed retraction spring" be in the "hollow body." Nowhere does claim 1 state that the compressed retraction spring must be in the nose. Furthermore, the "hollow body" is the "syringe body." Claim 1 states "A syringe comprising a hollow body with first and second open ends." '224 patent, Col. 18:38. Claims 25 and 39 are consistent with

[13]RTI did not include "prior to or during retraction" in its claim construction for "the needle holding portion is grounded on the annular shoulder." However, RTI did not state an objection to OMI's use of this language. Thus, the Court includes "prior to or during retraction" in the Court's construction as language that is not in dispute.

describing the hollow body as the syringe body. '224 patent, Col. 20:15 ("A syringe comprising a hollow body with first and second open ends"); Col. 21:41 ("A syringe assembly having a hollow body with an inside wall"). Accordingly, the Court construes "compressed retraction spring is positioned prior to retraction in an annulus disposed between the needle holding portion and the inside wall of the hollow body" as "the compressed retraction spring is positioned in the ring shaped space between the needle holding portion and the inside wall of the syringe body" and construes "a compressed retraction spring surrounding at least part of the elongated needle holding portion" as "the compressed retraction spring is positioned around at least part of the elongated needle holding portion."

OMI contends that claim 1 requires that the compressed retraction spring be located in the nose. OMI argues that because claim 1 requires both that "the needle holding portion is grounded inside the nose" and that "the compressed retraction spring is positioned between the needle holding portion and the inside wall of the hollow body," the spring must be inside the nose portion of the hollow body. '224 patent, Col. 18:64; Col. 19:1-3. However, being "grounded" only indicates where the distal, bottom end of the needle holding portion is located. The claim does not recite that the needle holding portion is located inside the nose. Furthermore, the needle holding portion necessarily extends above the point of grounding of the distal end to some proximal, top end—the location of which is unspecified in claim 1. Thus, OMI does not point to language that restricts the compressed retraction spring's location to be inside the nose.

OMI also contends that claim 43 requires that the compressed retraction spring be located in the nose. OMI argues that because claim 43 requires "a retraction mechanism disposed in the front end portion [of the hollow body]," the compressed retraction spring, as part of the retraction

mechanism, must be located in the nose. '224 patent, Col. 22:42-43. However, claim 43 only requires generally that the retraction mechanism is in the front end portion of the hollow body while not specifying that the compressed retraction spring is in the nose. Thus, OMI does not point to language that restricts the compressed retraction spring's location to be inside the nose.

OMI contends that the Summary of the Invention and the preferred embodiments show that the compressed retraction spring is restricted to a location inside the nose. OMI cites "The nose has a reduced diameter relative to the barrel. . . . A retraction mechanism is lodged *in the nose* of the body. The retraction mechanism comprises an elongated needle holder and *spring* combination wherein the needle holder has an elongated body with *a needle holding portion in front* and a head in back." '584 patent, Col. 3:6-7; 16-20 (emphasis added by OMI); *see also* '224 patent, Col. 3:19-20; 29-33. OMI states that all of the figures show the compressed retraction spring being positioned in the nose. Finally, OMI relies on the Summary of the Invention's description of the high blowout pressure, which states "[h]igh blowout pressure resistance is obtained because the retainer ring is mounted in the most constricted portion of the barrel where the nose begins which significantly reduces the amount of area exposed to fluid pressure." '584 patent, Col. 4:53-47; *see also* '224 patent, Col. 4:66-Col5:3. To suggest disavowal, OMI juxtaposes this citation with an excerpt from the Background of the Art: "[t]he prior art has not recognized a retraction mechanism . . . having resistance to . . . high blowout pressure." '584 patent, Col. 2:14-20.

OMI's citations to the specification are not persuasive in light of the claim language. Claim 1 unambiguously states that the compressed retraction spring is located in the hollow body, and OMI does not show clear disavowal. Nowhere does OMI cite that the compressed retraction spring is specifically located in the nose. While OMI points to descriptions in the specification where the

retraction mechanism, which includes the compressed retraction spring, is located in the nose, OMI does not point to any language indicating clear disavowal. Furthermore, the figures depicting the compressed retraction spring are not described as having disclaiming effect and thus do not limit the claims.

Finally, OMI argues that the high blowout pressure resistance is obtained because the retainer ring is mounted in the most constricted portion of the barrel where the nose is. However, the specification's reference to the high blowout system of the syringe does not state the location of the compressed retraction spring as in the nose. In fact, OMI's citation to the specification describing the high blowout system never mentions the compressed retraction spring. Also, OMI's juxtaposition of an excerpt from the Background of the Invention with an excerpt from the Summary of the Invention does not show clear disavowal. The patentee's description in the Background of the Art of what the prior art lacked and separate description of an advantage of the invention in the Summary of the Invention does not demonstrate clear intent to disavow the full scope of the claims. There is no evidence that the patentee meant for OMI's cited excerpt of the Background of the Art to be read directly with OMI's cited excerpt of the Summary of the Invention. Thus, the Court will not rewrite the claims as OMI proposes. Accordingly, the compressed retraction spring is not limited to being located in the nose.

CONCLUSION

For the foregoing reasons, the Court interprets the claim language in this case in the manner set forth above. For ease of reference, the Court's claim constructions are set forth in a table in Appendix B. The asserted claims with the disputed terms in bold are set forth in Appendix A.

So ORDERED and SIGNED this 10th day of August, 2009.

LEONARD DAVIS
UNITED STATES DISTRICT JUDGE

APPENDIX A

U.S. Patent #: 6,572,584

1. A reduced force syringe plunger handle for use in retracting a retractable syringe of the type having an elongated hollow syringe barrel having a front end portion containing a retraction mechanism activated by forward movement of the plunger relative to the barrel, the retraction mechanism comprising a rearwardly biased needle holder held by a separable **retainer member** lodged in the front end portion of the barrel, the **retainer member** having first and second sides oppositely disposed relative to a longitudinal axis through the barrel, the syringe plunger handle having a tubular body reciprocatably mounted in the barrel, the tubular body having a head comprising a **front tip** configured to contact and separate the **retainer member** from the needle holder by forward movement of the plunger relative to the barrel thereby releasing the needle holder for retraction, wherein the improvement comprises: the **front tip** of the plunger having a longitudinally varying front surface comprising a **first forwardly extending side configured to contact and move the first side of the retainer member relative to the needle holder and the barrel**, and a second forwardly extending side disposed rearwardly of the first forwardly extending side, **the second forwardly extending side configured to thereafter contact and move the second side of the retainer member relative to the needle holder and the barrel** when the plunger is moved forwardly relative to the barrel, thereby reducing the plunger force required to activate the retraction mechanism.

2. The reduced force syringe plunger handle of claim 1 wherein the longitudinal varying front surface is longitudinally stepped relative to the longitudinal axis through the barrel.

7. The reduced force syringe plunger handle of claim 1 wherein the first forwardly extending side of the longitudinally varying front surface tilts the **retainer member** relative to the needle holder and barrel prior to being contacted and moved by the second forwardly extending side.

18. A method of reducing plunger retraction force in a retractable syringe of the type having a barrel, a syringe plunger which reciprocates axially in the barrel and a front mounted retraction mechanism in the barrel having a retractable needle being held in position in the barrel by means of a **transverse retainer** which is separated from the retractable needle by contact between the **front tip** portion of the plunger and the **transverse retainer** when the plunger is moved forward after an injection to push the retainer off the retractable needle and allow retraction, comprising the step of: **providing a plunger having a front edge on the front tip portion configured to push on one portion of the retainer before pushing on the rest** of the retainer when the plunger is pushed forward at the end of an injection; pushing the plunger forward to bring the front edge of the tip portion in contact with the **transverse retainer member**; and tilting the **transverse retainer** with respect to the retractable needle while it is being separated from the retractable needle by forward movement of the plunger.

19. The method of claim 18 wherein the step of tilting the **transverse retainer member** with respect to the retractable needle while it is being separated from the retractable needle by forward movement of the plunger includes the step of separating one part of the **transverse retainer member** from the retractable needle before the rest of the **transverse retainer** is separated from the retractable needle.

20. The method of claim 18 wherein **the plunger is configured with a front edge** comprising an opening and a stepped rim around said opening having a high step and a lower step wherein the step of pushing the plunger forward comprises the step of bringing the high step into first contact with the **transverse retainer** before the lower step contacts the **transverse retainer**.

24. A method of reducing plunger retraction force in a retractable syringe of the type having a barrel, a syringe plunger which reciprocates axially in the barrel, and a front mounted retraction mechanism in the barrel having a retractable needle being held in position by means of a **transverse retainer** with an outside edge in contact with the inside surface of the front of the barrel wherein the **transverse retainer** is separable from the retractable needle upon forward movement of the plunger after an injection is made whereby a **front tip** portion of the plunger pushing against the

retainer moves the retainer forward in the front of the barrel thereby freeing the retractable needle, comprising the steps of: **providing a plunger having a front edge on the front tip portion configured to slide one portion of the outer edge of the transverse retainer with respect to the front of the barrel before beginning to move the rest** of the retainer with respect to the front of the barrel when the plunger is pushed forward at the end of an injection; and pushing the plunger forward to bring the front edge of the tip portion in contact with the **transverse retainer member**; and moving one portion of the **transverse retainer** with respect to the front of the barrel before moving the rest of the **transverse retainer** during forward movement of the plunger while the retractable needle is being separated from the **transverse retainer**.

25. The method of claim 24 wherein the steps of providing a plunger, bringing the front edge of the tip portion in contact with the **transverse retainer member** and moving one part of the **transverse retainer member** with respect to the front of the barrel before the remainder of the **transverse retainer** begins moving include the step of contacting the **transverse retainer** with the front edge of the plunger comprising an opening and a stepped rim around said opening having a high step and an lower step wherein the step of pushing the plunger forward comprises the step of bringing the high step into first contact with the **transverse retainer** before the lower step comes into contact with the **transverse retainer**.

U.S. Patent #: 7,351,224

1. A syringe comprising a hollow body with first and second open ends and an inside wall of varying inside diameter extending between the first and second open ends, a needle retraction mechanism insertable into the body through the second open end, a plunger having a forwardly extending plunger head insertable into the body through the second open end behind the needle retraction mechanism, and a needle extending forwardly of the first open end, wherein: the body comprises a nose adjacent to the first open end, a barrel adjacent to the second open end, and a transition zone connecting the barrel and nose; the needle retraction mechanism comprises an elongated needle holder, a compressed retraction spring, and a **retainer member**; the elongated needle holder further comprises a needle holding portion secured in fixed relation to the needle, a reduced diameter portion at one end of the needle holding portion, the reduced diameter portion extending forwardly through the first open end; a head at another end of the needle holding portion opposite the reduced diameter portion; a fluid path extending longitudinally through the needle holder in fluid communication with the needle and with a variable fluid chamber inside the body between the needle holder and the plunger; the **needle holding portion is grounded inside the nose adjacent to the first open end by a barrier limiting forward motion of the elongated needle holder inside a front portion of the nose prior to or during retraction**; the **compressed retraction spring is positioned prior to retraction in an annulus disposed between the needle holding portion and the inside wall of the hollow body**; the plunger head is aligned to separate the **retainer member** from the head of the needle holding portion and release the compressed retraction spring during retraction; and the plunger comprises a retraction cavity into which part of the retraction mechanism is received during retraction so that the needle no longer extends forwardly of the first open end.

3. The syringe of claim 1 wherein the inside wall of the body comprises an annular shoulder proximal to the first open end that is the barrier limiting forward motion of the elongated needle holder inside a front portion of the nose.

4. The syringe of claim 1 wherein **the plunger head further comprises a tip** forming an opening into the retraction cavity.

7. The syringe of claim 1 wherein the plunger head further comprises a seal slidably engaging the inside wall of the barrel.

8. The syringe of claim 7 wherein the seal is mounted in a fixed axial position on the plunger.

9. The syringe of claim 1 wherein the plunger further comprises a rear end portion opposite the plunger head, and a thumb cap at the rear end portion.

14. The syringe of claim 1 comprising a one-piece barrel.

18. The syringe of claim 1 wherein the needle is inserted into the reduced diameter portion of the elongated needle holder extending forwardly of the body and is attached to the elongated needle holder.

20. The syringe of claim 1 wherein the **retainer member** has an outside mating surface making a seal with the inside wall.

22. The syringe of claim 1 wherein the **retainer member** acts as a fluid seal for the variable fluid chamber prior to retraction.

23. The syringe of claim 1 wherein the plunger is vented.

43. A syringe assembly having a retractable needle that is rendered unusable after a single injection of fluid into a patient, the assembly comprising: a hollow syringe body comprising a barrel and having a front end portion and a back end portion, the back end portion further comprising at least one radially extending member providing finger grips for the syringe body; a retraction mechanism disposed in the front end portion, the retraction mechanism further comprising a needle holder having a head portion, an elongated needle holding portion, and a longitudinally extending fluid passageway through the head portion and the elongated needle holding portion, the head portion further comprising an inner head, **a continuous retainer member surrounding the inner head**, and a bridging portion disposed between **the continuous retainer member** and the inner head, wherein said bridging portion couples **the continuous retainer member** and the inner head to form a fluid seal between the fluid passageway and the barrel prior to retraction, and **a compressed retraction spring surrounding at least part of the elongated needle holding portion** and biasing the inner head toward the back end portion prior to retraction; a retractable needle extending into the front end portion of the body through an opening in the front end portion of the body, the retractable needle being held in fixed relation to the elongated needle holding portion of the needle holder and in fluid communication with the longitudinally extending fluid passageway through the head portion and the needle holding portion; a plunger reciprocally disposed inside the barrel and forming a variable chamber between the plunger and the needle holder prior to and during injection, the plunger being receivable into the barrel through the back end portion of the body and comprising an outer wall, a retraction cavity disposed inwardly of the outer wall, a plunger seal element providing sliding, sealed engagement between the plunger and the barrel and preventing fluid leakage between the plunger and the barrel, the plunger seal element being restrained from sliding longitudinally along the outer wall of the plunger, and a back end with an end cap having an outer periphery; and **a barrier disposed in the front end portion of the body that limits forward motion of the needle holding portion and the retractable needle relative to the body as the plunger is depressed inside the barrel during injection and retraction**; wherein **the continuous retainer member** is releasable from the inner head of the needle holder when the plunger is further depressed inside the barrel following injection.

44. The syringe assembly of claim 43 wherein the retraction mechanism is receivable through the back end portion of the barrel.

49. The syringe assembly of claim 43 wherein the barrel is not distorted during retraction.

50. The syringe assembly of claim 43 wherein the barrier is an annular shoulder disposed in the front portion of the barrel.

51. The syringe assembly of claim 50 wherein the annular shoulder is disposed adjacent to the opening in the front end portion of the body.

52. The syringe assembly of claim 50 wherein **the needle holding portion is grounded on the annular shoulder**.

55. The syringe assembly of claim 43 wherein the retraction cavity is vented behind the plunger seal element.

56. The syringe assembly of claim 55 wherein the retraction cavity is vented between the plunger seal element and the end cap.

57. The syringe assembly of claim 43 wherein the body comprises a one-piece barrel.

58. The syringe assembly of claim 43 wherein **the continuous retainer member** is coupled to the inner head with a holding force that exceeds a biasing force exerted on the inner head by the compressed retraction spring.

59. The syringe assembly of claim 43 wherein a portion of the elongated needle holding portion extends forwardly of the body.

60. The syringe assembly claim 43 wherein the continuous retaining member has an outside mating surface making a fluid seal with the barrel.

62. The syringe assembly of claim 43 wherein the bridging portion is frangible.

APPENDIX B

Term	Definition
retainer member **a continuous retainer member surrounding the inner head** **the continuous retainer member** **transverse retainer**	a non-retractable part of the retraction mechanism that uses some clamping or frictional force to keep the needle in the projecting position until released
first forwardly extending side configured to contact and move the first side of the retainer member relative to the needle holder and barrel **second forwardly extending side [of the front tip of the plunger] configured to thereafter contact and move the second side of the retainer member relative to the needle holder and barrel** **providing a plunger having a front edge on the front tip portion configured to push on one portion of the retainer before pushing on the rest** **the plunger is configured with a front edge** **providing a plunger having a front edge on the front tip portion configured to slide one portion of the outer edge of the transverse retainer with respect to the front of the barrel before beginning to move the rest**	[no construction necessary]
the plunger head further comprises a tip **front tip**	portion of the plunger closest to the needle
needle holding portion is grounded inside the nose adjacent to the first open end by a barrier limiting forward motion of the elongated needle holder inside a front portion of the nose prior to or during retraction	the needle holder abuts an obstruction in the nose of the syringe which prevents any forward movement by the needle holder prior to or during retraction
a barrier disposed in the front end portion of the body that limits forward motion of the needle holding portion and the retractable needle relative to the body as the plunger is depressed inside the barrel during injection and retraction	a structure located near the front end of the body that serves to prevent any forward movement of the needle holder prior to or during retraction
the needle holding portion is grounded on the annular shoulder	the needle holder is prevented from moving forward by a structure of reduced diameter within the syringe body prior to or during retraction

compressed retraction spring is positioned prior to retraction in an annulus disposed between the needle holding portion and the inside wall of the hollow body	the compressed retraction spring is positioned in the ring shaped space between the needle holding portion and the inside wall of the syringe body
a compressed retraction spring surrounding at least part of the elongated needle holding portion	the compressed retraction spring is positioned around at least part of the elongated needle holding portion